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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, by ELIOT SPITZER, Attorney General of the State of New York

Plaintiff,

-against-

GLAXOSMITHKLINE, PLC d/b/a GlaxoSmithKline,

SMITHKLINE BEECHAM CORPORATION d/b/a GlaxoSmithKline,

Defendants.

Civil Action No. ECFCASE

04 CV 5304

JUDGE CEDARBAUM

NOTICE OF REMOVAL

1. PLEASE TAKE NOTICE that, pursuant to 28 U.S.C. §§ 1441 and 1446 (federal question jurisdiction), Defendants GlaxoSmithKline plc ("GSK") and SmithKline Beecham Corporation ("SKB") remove this case to this Court. By removing this case, GSK does not waive its defense of lack of personal jurisdiction.

2. This case was filed as a civil action in the Supreme Court of New York for the County of New York on or about June 2, 2004. This removal is timely because SKB was served

with the complaint on or about June 8, 2004, and GSK was served with the complaint, at the earliest, on or about June 14, 2004. GSK and SKB have attached to this Notice of Removal a copy of the complaint, which as of the date of this Notice are the only papers on file in the Supreme Court in this case.

3. Venue is proper in the Southern District of New York under 28 U.S.C. § 1441(a) because this judicial district embraces the place where the action was pending.

4. Removal of this action is proper under 28 U.S.C. § 1441(a) & (b) because the claim made by Plaintiff Attorney General arises under the laws of the United States.

5. Pursuant to 28 U.S.C. § 1446(d), this Notice of Removal will be served on Plaintiff's counsel this 8th day of July, 2004, and will also be filed this day in the Supreme Court of New York for New York County.

6. The Attorney General's complaint on its face makes clear that his claims are founded on the Federal Food Drug & Cosmetic Act, 21 U.S.C. §§ 301 to 397 (the "FDCA").

7. The gravamen of the Attorney General's complaint is that GSK and SKB misrepresented the safety and effectiveness of Paxil® (paroxetine HCl) by failing to communicate to physicians reports of certain clinical studies of an unapproved or "off-label" use of Paxil® in pediatric patients. The Attorney General alleges that the studies in question failed to show that Paxil® was safe and effective for this unapproved use. Complaint ¶¶ 2, 4, 9, and *passim.*

8. As the Attorney General also alleges, *id.* ¶ 8, *see* ¶ 24, the standard for the safety and effectiveness of a prescription drug (such as Paxil®) is the standard applied by the U.S. Food & Drug Administration ("FDA"). That standard is set forth in the FDCA, 21 U.S.C. § 355(d), and FDA's regulations, 21 C.F.R. § 314.216.

9. An essential element of the Attorney General's case, therefore, is that GSK and SKB should have communicated to physicians reports of clinical studies, conducted in the United States under an FDA Investigational New Drug exemption, that failed to show safety and effectiveness in pediatric patients within the meaning of the FDCA and FDA's regulations. That essential element constitutes a substantial federal question for removal purposes under 28 U.S.C. § 1441(b). *West 14th St. Commercial Corp. v. 5 West Owners Corp.*, 815 F.2d 188, 196 (2d Cir. 1987) ("[A]ssuming that plaintiffs have no private right of action under [the federal statute at issue], we conclude that the federal element in plaintiffs' state cause of action would still be sufficiently substantial to confer arising under jurisdiction."); *Greenberg v. Bear, Stearns & Co.*, 220 F. 3d 22, 25, 26-27 (2d Cir. 2000) (finding federal jurisdiction because challenge to arbitration award presented substantial question of federal law, even though "[f]ederal law does not create the cause of action in this case"); *D'Alessio v. NYSE*, 258 F.3d 93, 100, 101 (2d Cir. 2001) (affirming removal based on substantial federal question; although complaint "alleges claims under the common law of New York," it "is rooted in violations of federal law"); *Bracey v. Board of Educ.*, 368 F.3d 108, 113 (2d Cir. May 11, 2004) (agreeing that state law "claims raise a substantial federal question because they necessarily turn on the construction of federal law").

10. The Attorney General's complaint is shot through with allegations that rest on the FDCA. Indeed, he even refers to Paxil® not by its proprietary name – "Paxil®" - but by its "established" name, "paroxetine." The established name of a prescription drug is exclusively a creature of the FDCA and is not owned by GSK. 21 U.S.C. §§ 352(e)(1)(A)(i), 358 (authorizing FDA to mandate established name and providing that a prescription drug is misbranded if its label fails to bear that established name "to the exclusion of any other nonproprietary name").

11. In ¶¶ 15 to 29 inclusive of the complaint, the Attorney General makes various allegations concerning certain clinical studies of Paxil® in pediatric populations. These studies could only have been conducted in the United States pursuant to Investigational New Drug exemptions issued by FDA under authority granted it in the FDCA.

12. In ¶ 46 of the complaint, the Attorney General alleges that GSK submitted the clinical studies to FDA as part of its application for approval of Paxil® for a pediatric indication. The submission of these studies was required by, and governed by, the FDCA.

13. In ¶ 53 of the complaint, the Attorney General alleges certain public statements made by FDA in so-called "Talk Papers." These FDA Talk Papers were issued by FDA pursuant to the FDCA.

14. In ¶¶ 48 to 52, & 54 -55 of the complaint, the Attorney General alleges a conflict between federal regulatory standards for drug approvals under the FDCA in the United States compared to the standards in Canada, the United Kingdom, and the European Union.

15. The primary relief sought by the Attorney General is injunctive. *E.g.*, Complaint ¶ 5 (alleging that the Attorney General "brings this action to stop GSK's illegal and deceptive actions . . . .").

16. A case such as the Attorney General's complaint here arises under federal law for purposes of 28 U.S.C. § 1441(b), "where the vindication of a right under state law necessarily turn[s] on some construction of federal law." *D'Alessio*, 258 F.3d at 99 (quoting with approval *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 9 (1983)).

17. The federal question, however, must be "substantial." *D'Alessio*, 258 F.3d at 99 ("[I]n cases where 'state law creates the cause of action, [we] ask[] whether that cause of action poses a substantial federal question.'") (alterations added and in original) (quoting with approval

West 14th St., 815 F.2d at 192); *accord City of Chicago v. International College of Surgeons*, 522 U.S. 156, 164 (1997) (affirming removal of complaint based on Illinois law because the "right to relief under state law requires resolution of a substantial question of federal law") (quoting with approval *Franchise Tax Bd.*, 463 U.S. at 13); *General Mar. Mgmt., LLC v. St Shipping & Transp., Inc.*, 2004 WL 1320893, at *4 (S.D.N.Y. June 10, 2004) (holding against federal jurisdiction but noting that a substantial question of federal law exists where claims "necessarily depend" on construction of federal law).

18. In this Circuit, there is no categorical requirement that the federal statute at issue provide a private right of action for the federal question to be "substantial" for purposes of removal. *West 14th St.*, 815 F.2d at 196 ("[A]ssuming that plaintiffs have no private right of action under [the federal statute], we conclude that the federal element in the plaintiff's state cause of action would *still be sufficiently substantial* to confer arising under jurisdiction.") (emphasis added); *Bracey*, 368 F.3d at 114 (Second Circuit has not "categorically" precluded federal question jurisdiction in the absence of a federal private right of action (quoting *Barbara v. NYSE*, 99 F.3d 49, 54 (2d Cir. 1996)); *Platzer v. Sloan-Kettering Inst. for Cancer Research*, 787 F. Supp. 360, 366 (S.D.N.Y. 1992) ("[E]ven where no private right of action exists for the underlying federal issue, if the nature of the federal issue is sufficiently substantial, subject matter jurisdiction may still exist . . . ."). *But cf. Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 814 and n. 12 (1986) (product liability case not involving injunctive relief; finding no substantial federal question because FDCA did not provide private right of action for damages, but noting that this issue requires "an evaluation of the *nature* of the federal interest at stake") (emphasis added).

19. Unlike the personal injury product liability action at issue in *Merrell Dow*, the Attorney General here, acting as an officer of state government, seeks injunctive relief to address remedies that are peculiarly within the province of FDA - the communication to physicians of information about an off-label use of a prescription drug. He does not state whether he intends for this injunction to run nationwide, but since he is suing to enforce a federal standard the injunction he seeks likely will be national in scope. This case is dramatically different from *Merrell Dow*.

20. In any event, there is a federal remedy under the FDCA for the injunctive relief sought by the Attorney General in his complaint. The Attorney General seeks an injunction to prevent GSK and SKB from (allegedly) failing to communicate to physicians reports of the clinical studies at issue. FDA has the statutory authority to grant such relief under the "misbranding" provisions of the FDCA. 21 U.S.C. §§ 331(a) & 352(a). This relief could include requiring that a "Dear Doctor" letter be distributed to physicians or that changes be made to the prescribing information for PAXIL®. *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645, at *3 (S.D.N.Y. Nov. 22, 2000) (noting that FDA has authority over labeling and "Dear Doctor" letters).

21. FDA's regulations, 21 C.F.R. § 10.30, provide for the Attorney General to file a citizen petition with FDA, which FDA will act upon within 180 days. *Id.* § 10.30(e)(2). FDA receives – and acts upon - about 200 citizen petitions each year, many of which are submitted by major pharmaceutical companies. The citizen petition is a recognized and well-established procedure for obtaining from FDA exactly the type of order the Attorney General seeks in the form of an injunction. *E.g.*, Citizen Petition of Pharmacia Consumer Healthcare, FDA Docket

No. 01P-0122 (filed Mar. 7, 2001), *granted* (May 10, 2002) (change in labeling of prescription drug).

22. If FDA denied the Attorney General's citizen petition, the Attorney General could then institute an action in federal court, seeking *exactly* the injunctive relief he seeks here under the federal Administrative Procedure Act. 5 U.S.C. § 702 (providing for judicial review and authorizing federal court to enter a "mandatory or injunctive decree").

23. The citizen petition, and a subsequent action for judicial review, are remedies that fully support the existence of a substantial federal question here. *In re Wireless Tel. Radio Frequency Emissions Prods. Liab. Litig.*, 216 F. Supp.2d 474, 481 n. 4 (D. Md. 2002) (finding substantial federal question and upholding removal on ground that petition to administrative agency and judicial review "demonstrate Congressional intent to support plaintiffs' right to adequate protection" from alleged hazards of cellphones); *Little v. Purdue Pharma, L.P.*, 227 F. Supp.2d 838, 859-60 (S.D. Ohio 2002) (remanding product liability damages action to state court, but noting that if action had sought injunctive relief, "then the Court would be more inclined to view the cause of action as encompassing nothing more than that which the administrative action provides") (citing FDA citizen petition regulation, 21 C.F.R. § 10.30).

24. In addition to injunctive relief, the Attorney General also seeks "disgorgement" of profits GSK and SKB derived from the sale of Paxil® for pediatric patients in New York. Complaint ¶ 5, Prayer for Relief. FDA has obtained disgorgement of profits from drug manufacturers in enforcement actions. *See, e.g., United States (FDA) v. Schering-Plough Corp.*, No. C-02-2397, Consent Decree (D.N.J., filed May 20, 2002) (providing for disgorgement of $500 million in profit for failure to comply with FDA's good manufacturing practices).

25. In summary, the Attorney General's complaint on its face alleges a substantial federal question under the safe and effective standard for prescription drugs in the FDCA. In the Second Circuit, it is not a prerequisite for a substantial federal question that the underlying federal statute provide a private right of action, especially where, as here, the plaintiff is a state government official seeking an injunction of national scope. In any event, the Attorney General does have a fully effective federal remedy for all the relief he seeks. Since his complaint alleges a substantial federal question, it is properly removed to this Court pursuant to 28 U.S.C. § 1441(b).

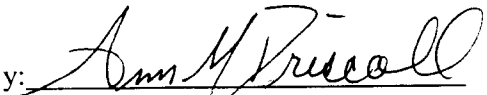
WHEREFORE, the defendants pray that this Court will assert jurisdiction over this action.

Dated: New York, New York

July 8, 2004

Respectfully submitted,

KING & SPALDING LLP

By: 

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